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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/675,892	09/29/2000	Bruce L. Gibbins	01005.0111 - 41946.247727	3382

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EXAMINER

HAMILTON, LALITA M

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 11/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/675,892

Applicant(s)

GIBBINS ET AL.

Examiner

Lalita M Hamilton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on after final filed on November 4, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16 and 18-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 10-16 and 18-20 is withdrawn in view of the newly discovered reference(s) to Friedman (5,023,082). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nangia in view of Friedman (5,023,082).

Nangia discloses the invention substantially as claimed; however, Nangia does not disclose the active agent directly incorporated into the matrix without the prior incorporation of the active agent into another delivery vehicle. Friedman teaches a polymeric matrix for the sustained release of an active agent comprising an active agent directly incorporated into the matrix without the prior incorporation of the active agent into another delivery vehicle (col.3, lines 53-58; col.4, lines 15-21; and col.9, lines 14-22 and 35-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to directly incorporate the active agent into the matrix with prior incorporation into another delivery vehicle to maximize the effect of the agent.

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Claims 11, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nangia and Friedman as applied to claim 10 above, and further in view of Romans.

Nangia discloses and Friedman teaches the invention substantially as claimed; however, neither reference discloses nor teaches the active agent comprising one or more metals, the addition of a stabilizing solution, or copper chloride. Romans teaches a composition for use in treating wounds comprising metals (col.2, lines 3-10), a stabilizing agent, and copper chloride (col.1, line 60 to col.2, line 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the metals and stabilizing solution comprising copper chloride as taught by Romans into the device disclosed by Nangia to deter the growth of microbes in the wound.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nangia, Friedman, and Romans as applied to claim 14 above, and further in view of Hara.

Nangia discloses and Friedman and Romans teach the invention substantially as claimed; however, none of the references disclose nor teach the use of ferric chloride. Hara teaches a medical composition utilizing ferric chloride in an antiseptic (col.3, lines 60-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the ferric chloride as taught by Hara in place of the stabilizing solution disclosed by Romans as an alternative stabilizing agent.

Claims 18-22 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nangia in view of Romans and Friedman.

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Nangia discloses the invention substantially as claimed; however, Nangia does not disclose a stabilizing solution, sustained release of the active agent, the agent being metal or salt, tetracycline, or penicillin. Nangia teaches a stabilizing solution and the active agent comprising a metal or salt (col.2, lines 3-10 and col.1, line 60 to col.2, line 10). Friedman teaches the sustained release of the active agent in a polymeric matrix (col.4, lines 55-60), penicillin, and tetracycline (col.6, lines 35-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the stabilizing solution and metal and salt taught by Romans into the device disclosed by Nangia to deter the growth of microbes in the wound and to provide sustained release of the active agent, tetracycline, and penicillin to maximize the effect of the agent.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nangia, Romans, and Friedman as applied to claim 21 above, and further in view of Edelman.

Nangia discloses and Romans and Friedman teach the invention substantially as claimed; however, none of the references disclose nor teach growth factors. Edelman teaches a device for the controlled release of growth factors, such as fibroblast derived growth factors (col.2, lines 50-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate fibroblast derived growth factors taught by Edelman into the device disclosed by Nangia as an alternative active agent.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-

2272

LMH



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November 18, 2002